Melissa Walker, MS, RAC

Contact information

Melissa Walker, MS, RAC
4041 Forest Park
St. Louis, MO 63108

Phone: 314-615-6351
Fax: 314-615-6948
e-mail: Mwalker@stereotaxis.com

Summary

Skilled executive with proven expertise in business, regulatory affairs and clinical research. Recognized for strategic business focus and innovative approaches to regulatory strategies and process development/improvement. Skills and professional achievements:

- Possesses a broad base of business, regulatory, quality and clinical research experience working with a variety of medical products. Therapeutic areas include cardiology, immunology, dermatology, ophthalmology, oncology, gastroenterology, diabetology, and gynecology.
- Worked with biotechnology start-up companies as a volunteer advisor, assisting them with development and regulatory strategies.
- Developed and implemented worldwide regulatory, post-market surveillance, and clinical research systems to support the development, manufacturing, and marketing of medical products.
- A skilled communicator and presenter to large or small audiences.
- Former Chairman of the Board of the Regulatory Affairs Professionals Society and served on the board of directors from 1997 to 2001.

Education & certifications

Education, degrees, and certifications obtained are as follows:

School/Institution:	Degree/ Certification	Discipline
East Texas State University Commerce, Texas	BS	Biology Animal Science
East Texas State University Commerce, Texas	MS	Zoology
Indiana University/Purdue University, Indianapolis, Indiana	--	Post-Graduate Hours Pharmacokinetics
Regulatory Affairs Certification Board	RAC	Regulatory Affairs
Harvard Business School	--	Superior New Product Development
Kellogg Graduate School of Management, Northwestern University, Chicago, Illinois	--	Executive Development for Regulatory Professionals

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2001 to present *Vice President, Regulatory Affairs and Quality Systems*
Stereotaxis, Inc., St. Louis, MO

Stereotaxis, Inc. is a medical device company specializing in magnetically guided surgical systems used in interventional cardiology and neuroradiology.

Responsible for the regulatory affairs, quality systems, and clinical research (2001-2004) functions, including submissions, complaint-handling, regulatory compliance, clinical studies and strategic planning. Reports to the CEO and serves on the management board.

1997 to 2000 *Executive Director, Global Regulatory Affairs*
Bausch & Lomb Surgical, Inc., St. Louis, MO

Bausch & Lomb Surgical was a global medical device company that produced surgical instrumentation, equipment, and implants for ophthalmologists. Included are devices for cataract, posterior and anterior segment surgery and refractive correction.

1995 to 1997 *Director, Regulatory Affairs*
1995 to 1995 *Manager, Regulatory Affairs*
1992 to 1995 *Project Manager, Regulatory Affairs*
Ethicon Endo-Surgery, Inc., Cincinnati, Ohio

Ethicon Endo-Surgery, a division of Johnson & Johnson, is a global medical device company that produces surgical instrumentation for open and minimally invasive surgical procedures.

Overall responsiblity for worldwide regulatory submissions of products in over 100 countries, as well as complaint-handling and adverse event reporting. Developed and implemented a computer-based regulatory information management system (e.g., product information, submissions tracking).

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1989-1991

Manager, Clinical Studies
Walker Clinical Evaluations, Inc., Indianapolis, IN

Walker Clinical was a site management organization that carried out studies for prescription pharmaceuticals, OTC medications, medical devices, in-vitro diagnostics, cosmetics, and personal care products on a contract basis for medical product manufacturers.

Responsible for conducting clinical trials. Duties included protocol and CRF development, investigator identification, IRB review, subject recruitment, study execution, and report generation. Supervised staff on a project basis.

1986 to 1989

Manager, Regulatory & Compliance Services
Sr. Administrator, Regulatory & Compliance Services
Regulatory Assistant, Regulatory Affairs
Technical Evaluation & Management Systems, Inc. (TEAMS), Dallas, TX

TEAMS was a full-service contract research organization that provided regulatory, clinical, statistical, and data management services to the medical product industry.

Responsibilities included creation and administrative coordination of drug and medical device submissions (IND, NDA, IDE, PMA, and 510(k)). Developed and organized research plans with regulatory strategies. Planned and led inter-departmental efforts for QA of clinical/statistical reports.

1979 to 1985

Other positions held during this time were:

- Owner/Operator of a retail pet store
- Instructor and Learning Associate, Biology Department, Mountain View College, Dallas, Tx
- Assistant Instructor, Biology Department, East Texas State University, Commerce, TX